DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 5 1999

NDA 19-614/S-027

Elan Pharmaceutical Research Corp.
Attention: Roger Wayne Wiley, R.Ph.
1300 Gould Drive
Gainesville, GA 30504

Dear Mr. Wiley:

Please refer to your supplemental new drug application dated August 27, 1998, received August 31, 1998, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Verelan (verapamil hydrochloride) Capsules.

We acknowledge receipt of your submissions dated March 23, 1999. Your submission of March 23, 1999 constituted a complete response to our January 27, 1999 action letter.

This supplemental new drug application provides for draft labeling revised to include a **Geriatric Use** subsection under **PRECAUTIONS:**

> Clinical studies of verapamil did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 23, 1999).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-614/S-027." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.